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September 10, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0228

Dear Sir/Madam:

We are writing to comment on FDA's Implantable Middle Ear Hearing Device (IMEHD); Draft Guidance For Industry And FDA. The Hearing Industries Association (HIA) is the trade association representing hearing health device manufacturers and their suppliers.

In its Draft Guidance, FDA requires manufacturers to use the test methods in ANSI/IEEE C63.19-2001 American National Standard for Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids. See § 4 Preclinical Information, Electromagnetic Compatibility (EMC) Testing at 7. HIA questions the use of this standard for the following reasons:

1. The standard was developed for air conduction hearing aids. Past and ongoing testing regarding the standard have been accomplished on air conduction hearing aids exclusively. An implantable middle ear hearing device (IMEHD) is an implantable device and the standard was not necessarily designed for implantable devices. To our knowledge, the standard has never been tested on implantable devices.

2. The standard as it now reads will provide inconclusive data at best because it was never meant to measure an implantable device and makes no consideration for human tissue or the significant differences in the design and function of an IMEHD.

3. The standard is flawed. In continuing laboratory tests of the standard in the US and in Europe using digital cellular phones and air conduction hearing aids, a recurring problem is that tests results are not repeatable. In some cases, the same hearing aid, when subjected to multiple tests, returned a range of immunity data. It is the opinion of industry engineers that the custom nature of hearing aids substantially affects the ability to achieve repeatability. For this reason, HIA voted against the standard when under consideration by ANSI.

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4. Because the ANSI standard is flawed, HIA members along with hearing instrument manufacturers in Europe and Australia have chosen not to adopt the standard for measuring the immunity of air conduction hearing aids from digital cellular phones.

5. Testing of the ANSI standard as well as other international standards continues in both the US and Europe with the goal of devising a more accurate method of measurement. At this time, the ANSI standard does not provide the level of accuracy necessary for the testing of a medical device and applying the standard to IMEHDs would not benefit the public health.

HIA believes that inclusion of ANSI/IEEE C63.19-2001 as a guidance requirement would provide little if any data that would enhance public safety. Indeed, use of the standard for testing may prove confusing to both the industry and agency. The ANSI standard is not appropriate for measuring immunity and therefore should not be included in the Draft Guidance.

HIA suggests that further testing be conducted regarding the IMEHD's immunity characteristics similar to testing undertaken for air conduction hearing aids and pacemakers. Test data would provide a basis of knowledge to identify if an interference issue exists and the best course of action to measure any interference.

HIA also believes it is important for the agency to clarify the following in the Draft Guidance:

- FDA cites "ISO/IEC 12207: Information technology software life cycle processes (Software), Information Technology – Software Life Cycle Processes" as a standard that may be used and to which manufacturers may provide statements or declarations of conformity. See § 3 Manufacturing, Software Validation at 3. HIA believes both FDA and manufacturers would benefit if the agency clarified exactly how this standard can be used, *i.e.,* what sections of the standard can a manufacturer declare conformity to and therefore not submit the related data and information in the PMA.

- According to the Draft Guidance, all IMEHDs labeled sterile should have expiration dating that is determined by assessing the barrier properties of the packaging to assure sterility. FDA states, "In addition, certain devices should be tested to assure that storage and shipping conditions do not alter their function and that they function the same as when manufactured." See § 3 Manufacturing, Sterilization at 4. FDA should clarify exactly which devices require additional testing and provide a rationale for its reasoning.

- The agency should clarify its requirements on animal studies. For example, in describing what information animal studies reports should include, FDA twice lists "type and number of animals used," once independently and once under "experimental design." See § 4 Preclinical Information, Animal Studies at 6. The agency should clarify whether this repeated listing was intentional, and if so, should state if different

clarify whether this repeated listing was intentional, and if so, should state if different information is sought for each entry. FDA also should clarify what is the sufficient length of animal studies to allow for evaluation of tissue remodeling.

- FDA states that IMEHD manufacturers "should specify the recommended type of anesthesia." See § 5 Investigational Device Exemptions, Surgical concerns at 14. HIA questions whether practical limitations are placed on manufacturers in making such a recommendation.

- FDA may want to provide examples of design changes that would trigger a PMA supplement. See § 7 Modifications of Approved Devices at 16.
- Are manufacturers required to name other manufacturers in the agency's proposed informed consent? See Appendix A Informed Consent at 17 (requiring manufacturers to "discuss other implantable middle ear hearing devices and other recognized communicative systems and devices, such as conventional acoustic hearing aids.").

- FDA identifies the following precaution: "Theft and metal detection systems may activate the detector alarm of these systems. Therefore, patients should carry their Patient Identification Card with them at all times." See Appendix B Labeling, Precautions at 20. Presumably, FDA meant "IMEHDs may activate the detector alarm of theft and metal detection systems." The agency should clarify this statement.

Thank you for considering our comments. HIA appreciates the opportunity to comment on this Draft Guidance.

Sincerely,

Carole M. Rogin
Executive Director

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